August 18, 2003

Background Material Re: Sunlamp Products for TEPRSSC members

History: Relevant events since last TEPRSSC meeting

October 1-2, 2002: International committee for sunlamps (IEC TC 61, MT 16) met in London. Several items were discussed, including:

(1) incorporation of the new CIE action spectrum for non-melanoma skin cancer[1] (NMSC) to evaluate long-term risks of exposure to UV radiation,
(2) replacement lamps (it was decided that Ulf Wester, Radiation Protection Institute, Sweden would serve as the liaison between IEC MT 16 and IEC SC 34A which is the committee that has responsibility for preparing standards for testing of individual UV lamps). It was hoped that a concrete proposal could be developed prior to the next IEC TC 61 MT 16 meeting in Helsinki
(3) classification of sunlamp products according to their effective output. It was decided to use the NMSC action spectrum to classify lamps and to add an additional class (type 5) to include products that have been up to now excluded by the present classification system.
(4) An absolute cap of UV irradiance of 1 W/cm^2-effective (weighted with the NMSC action spectrum) was accepted.

June 3-5, 2003: IEC TC 61, MT 16 met in Helsinki, Finland. Several items were discussed, including:

(1) a detailed evaluation of the Instructions for Use, some changes were made including limiting the use of these products by minors.
(2) Replacement lamps. Members of IEC SC 34A attended and a compromise was reached on how to evaluate and designate UV lamps according to their biologically-effective output. The details of that decision are described in item # 7 in the body of this report.

June 28, 2003: Joint meeting of the FDA, American Academy of Dermatology (AAD) and American Society for Photobiology (ASP) on Tanning. This meeting was initiated by Dr. Howard Cyr, CDRH to improve communications with the dermatology community as they have expressed concern over increasing use of indoor tanning. Howard Cyr discussed the FDA standard for sunlamps and stated that although FDA had received a request to ban sunlamps for indoor tanning in 1995, that FDA had no plans to do this in the immediate future. Therefore, FDA has taken the approach of conducting research to improve the science of UV exposure to humans and to improve education and regulations. Janusz Beer and Sharon Miller of CDRH presented results of their research on human subjects.

Representatives from the AAD presented results from surveys that showed an increase in the use of indoor tanning equipment, especially by young women and increases in skin

cancer cases over the last few decades. They asked the FDA to make the warnings against indoor tanning stronger and plan to send petitions to the FDA Commissioner to this effect.

Proposed Amendments

1. Warning Label

   Existing Label:

   DANGER-Ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer. WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp is you have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from use of this product.

   Proposed Revised Label:

   WARNING - Ultraviolet radiation may cause:
   - injury to the eyes and skin
   - skin aging
   - skin cancer.

   Read instructions carefully.
   Wear protective eyewear provided.
   Certain medicines and cosmetics may increase sensitivity to ultraviolet radiation.

   * Lettering of at least ten (10) millimeters height for the word "Warning" and five (5) millimeters for the rest of the label information is recommended to meet the visibility requirements specified in 1010.3.

2. Inclusion of label into catalogues, specification sheets, and descriptive brochures.
   FDA proposes: ".. in all catalogs, specifications sheets, and descriptive brochures and any other purchasing information pertaining to each sunlamp product and ultraviolet lamp, a legible reproduction of the warning statement required by 21 CFR 1040.20 shall be affixed"

3. Significant modification of a sunlamp product means recertification as a "manufacturer"

"The modification of a sunlamp product, previously certified under 1010.2, by any person engaged in the business of manufacturing, assembling, or modifying sunlamp products shall be construed as manufacturing under the act if the modification affects any aspect of the product's performance or intended function(s) for which this section has an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the product in accordance with the provisions of 1010.2 and 1010.3. Examples of types of modifications that will affect the product's performance are (1) replacing the lamps in the sunlamp product with lamps that would not be considered 'compatible' based on the definition for compatibility described in the FDA policy letter of September 2, 1986.

Briefly:

"A replacement lamp will be considered compatible with (or equivalent to) another (original) lamp if:

(1) The replacement lamp will not cause any sunlamp product intended to use the original lamp to fail to comply with the standard or to become defective as defined by 21 CFR 1003.2, and;
(2) the lamp is as effective, within plus or minus ten percent, as the original lamp, in causing erythema and melanogenesis."

However, in the interest of harmonization with the international standard for sunlamps (IEC 3-225-27), the requirement that the lamp's effectiveness be compared on the basis of melanogenesis will be removed and a new requirement based on the CIE non-melanoma skin cancer action spectrum will be added. See item # 7.

4. Protective Eyewear Requirements:

Current language in standard: "the spectral transmittance shall not exceed a value of 0.001 over the wavelength region 200 to 320 nm, and a value of 0.01 for 320 to 400 nm, and shall be sufficient over the wavelength region > 400 nm to enable the user to see clearly enough to reset the timer"

Proposed:

? ? Same UV limits
? ? For Visible region (> 400 nm), a more quantitative definition: "the luminous transmittance[2] shall not be less than 1% over the 380 to 780 nm wavelength region "and the unweighted transmittance ($\leq$ 5 nm intervals) over the 400 to 550 nm region shall not exceed 5%". This second requirement is currently part of the international standard for sunlamp products (IEC 6-335-2-27).

5. Replace the currently-used 'CIELYTLE' erythema action spectrum with the internationally-accepted CIE Reference action spectrum for erythema[3].

6. Adopt a maximum timer setting of 3 minimal erythema doses (MEDs) where MED is defined as 200 J/m^2-effective (wavelength-weighted with the CIE erythema action spectrum. The limit of 3 MEDs provides a biologically-equivalent dose to what is currently used; i.e. 4 MEDs, weighted with the CIELYTLE action spectrum and assuming that 1 MED = 156 J/m^2-effective. Both limits, the 'old' 4 MEDs using CIELYTLE action spectrum and the 'new' 3 MEDs using latest CIE action spectrum, are roughly equal to 600 J/m^2-effective.

7. For determining replacement lamps (low pressure, fluorescent types), the following coding scheme shall be used:

   Wattage – Reflector type code – UV code

   where the Wattage is the nominal lamp wattage, marked "watts" or "W", the reflector type code is defined as follows: (? is the angle subtended by the non-reflective circumference of the lamp tube)

O	for non-reflector lamps	
B	for lamps with a broad reflector angle	? > 230°
N	for lamps with a narrow reflector angle	? < 200°
R	for lamps with a regular reflector	200° ≤ ? ≤ 230°

   The following UV code shall be used:

   UV code = X/Y

   where X = total erythema effective UV irradiance over the range 250 to 400 nm; and Y = the ratio of the CIE non-melanoma skin cancer action spectrum[3] (NMSC) effective UV irradiances ≤ 320 nm and ≥ 320 nm.

   X is to be specified in mW/m^2, rounded to the next integer, Y is to be rounded to the first decimal. The effective values are calculated at a measurement distance of 25 cm and under conditions of optimum UV irradiance as described in IEC 61228 – Method of Measuring and Specifying Fluorescent Ultraviolet Lamps used for Tanning.

   Lamps will be considered to be acceptable replacements if the X and Y components of the UV code are within 10% of those of the original lamps. The sunlamp product shall be labeled with the substance of the following:

(For example, where the original lamp in the sunlamp product had a code of **100 – O – 47/3.2**)

"Use only replacement lamps with the following range of UV code printed on them:
100 – O – (42 to 52)/ (2.9 to 3.5)"

Notes/References

1. CIE 138/2 Action spectrum for photocarcinogenesis (non-melanoma skin cancer) CIE Central Bureau, Kegelgasse 27, A-1030 Vienna, Austria.
2. Luminous transmittance is defined by the following formula; taken from American National Standard ANSI Z87.1, 2003: Practice for – Occupational and Educational Eye and Face Protection, American National Standards Institute, New York, NY.

$$\frac{\int_{380}^{780} T(?)y(?)S(?)d?}{\int_{380}^{780} y(?)S(?)d?}$$

where y(?) is the relative luminous efficiency function and S(?) is the relative spectral emittance of Illuminant A as defined by the CIE. These functions can be found in Table A2 of Appendix A of this standard.

3. CIE S 007/E-1998, Erythema Reference Action Spectrum and Standard Erythema Dose, CIE Central Bureau, Kegelgasse 27, A-1030 Vienna, Austria.